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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/453,109 12/02/99 PRAUSNITZ

M GTRC-2139

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QM22/0613

EXAMINER

KREMER, M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/453,109

Applicant(s)

PRAUSNITZ ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There was no mention in the specifications of a material contained in the microneedle which modulated the flow of the biological fluid.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

and

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-4, 10, 27, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent Application Publication JP07132119A to Yoshihiko (cited by Applicant). Yoshihiko discloses a blood collecting device which includes a substrate 1 with a plurality of microneedles 11, and a collection chamber (where the number 12 is located). In regard to claims 2 and 4, the membrane 12 is deformed which increases the volume of the collection chamber when heat is generated from the microheater 3 as stated in lines 7-9 of the constitution of Yoshihiko. In regard to claims 3 and 29, the blood is collect by a negative pressure in the collection chamber as stated in lines 9-10 of the constitution of Yoshihiko.

5. Claims 1-4, 7, 9, 12-13, 15, 18-20, 22-23, 25, 27, 29, 31-34, and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,080,116 to Erickson et al. Erickson et al. discloses a collection apparatus for minimally-invasive testing of a body fluid constituent as disclosed in column 5, lines 8-60. A preferred embodiment of the apparatus is given in Figs. 2 and 3 and described in column 6, line 40 to column 8, lines 31. The apparatus includes a capillary tube 12 and hollow tube 42 which are inserted into the dermal layer of the skin. Interstitial fluid is urged up the tube by capillary action, negative pressure, or compressing the skin. In regard to claims 2-4, 7, 12-13, 28-29, and 33-34, a vacuum system with a plunger creates a negative pressure which provides an additional force to urge the fluid into the inner chamber 76. In regard to claim 9, the capillary tube 12 is one collection chamber and the inner chamber 76 is another. In regard to claims 12-13, the plunger acts as a controlling

means. In regard to claims 15, 18-20, and 22-23, Erickson et al. teaches a sensor method for glucose as stated in column 8, line 32 to column 10, line 11. In regard claim 25, the needle has openings as stated in column 8, lines 36-38.

6. Claims 1-2, 10, 24, 27-28, 30, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by International Application Publication WO 98/00193 to Eppstein (cited by Applicant). Eppstein discloses a method of transdermal monitoring on page 5, lines 14 to page 6, line 22 which includes a device comprising a base, a plurality of puncturing members, and a reservoir. In regard to claim 1, the device of Eppstein collects a sample of blood. In regard to claims 2 and 28, the interstitial fluid moves by capillary action. In regard to claim 24, Eppstein teaches on page 13, lines 28-32 that the fluid can be analyzed according to known methods such as various test strips for glucose. In regard to claim 30, Eppstein teaches that one illustrative analyte is glucose. In regard to claim 36, Eppstein discloses that the method is used for puncturing a selected layer of the skin.

7. Claims 1-2, 14-17, 19-21, 23, 27-28, 30-32, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,801,057 to Smart et al. (cited by Applicant). Smart et al. discloses a blood sampling and analyzing device using a very fine, short, hollow needle through which blood can be drawn by capillary action into a small sampling chamber. An analysis of this sample for determination of glucose or some other biological analyte is carried out by means of a combination of chemical

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reagents and optical transmittance measurements as stated in column 3, lines 23-31.

In regard to claims 14-17 and 21, Smart et al. discloses that the collection chamber and needle may incorporate a reagent which facilitates the measurement of the analyte as stated in column 7, lines 38-65. An example is given in which glucose is the analyte and glucose dehydrogenase is the reagent.

8. Claim 15-24, 31, 35, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,807,375 to Gross et al. Gross et al. discloses an analyte monitor which includes a means for detecting the concentration of an analyte which includes a sensor needle extending from the lower surface of a housing. The sensor needle has an outer end projecting a sufficient distance so as to penetrate into the dermis when the housing is pressed against the skin as stated in column 6, lines 35-42. In column 6, line 66 to column 7, line 61, Gross et al. discloses the sensing component of the sensor needle. In regard to claims 16-17 and 21, the enzyme is glucose oxidase as stated in column 8, lines 31-32. In regard to claims 19, 23, and 35, the analyte is glucose as stated in column 8, lines 24-26.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,080,116 to Erickson et al. as applied to claim 4, in view of U.S. Patent 5,364,374 to Morrison et al. (cited by Applicant). In column 7, lines 34-53, Erickson et al. teaches that the interstitial fluid is urged by the capillary tube by various means including negative pressure. Erickson et al. does not disclose the use of standard or Luer-lock syringe. It is well known in the art that a syringe provides a negative pressure to create the suction for withdrawing fluid. Morrison et al. discloses a microneedle connected to a syringe as stated in column 2, lines 26-40. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interstitial fluid collection apparatus of Erickson et al. to include a syringe as disclosed by Morrison et al. since Erickson et al. teaches that a negative pressure is used to urge the fluid in the capillary tube and a syringe creates a negative pressure.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,080,116 to Erickson et al. as applied to claim 4, in further view of U.S. 4,703,761 to Rathbone et al. In column 7, lines 34-53, Erickson et al. teaches that the interstitial fluid is urged by the capillary tube by various means including negative pressure. Erickson et al. does not disclose that the collection chamber comprises an upper portion which is formed of a material which is deformable. Rathbone et al. teaches in column 1, lines 34-42 that a procedure for drawing blood involves the use of a flexible plastic bulb which is connected to a collecting tube and is manually squeezed

to create negative pressure for drawing the blood sample. This device operates in a manner similar to an eye dropper. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interstitial fluid collection apparatus of Erickson et al. to include a flexible plastic bulb as disclosed by Rathbone et al. since Erickson et al. teaches that a negative pressure is used to urge the fluid in the capillary tube and a compressed flexible plastic bulb which is depressed creates a negative pressure.

12. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,080,116 to Erickson et al., in further view of U.S. 4,703,761 to Rathbone et al. as applied to claim 6, and in further view of U.S. Patent 4,664,651 to Weinshenker et al. The combination does not teach a one-way valve. Weinshenker discloses a check valve located in a flexible bulb which allows the air contained in the bulb to flow into the atmosphere each time the bulb is manually squeezed as stated in column 6, lines 49-66. A check valve would prevent the need to keep the bulb manually compressed during insertion into the skin or pushing air into the patient's tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include a check valve as disclosed by Weinshenker et al. since it would prevent the need to keep the bulb manually compressed during insertion of the apparatus into the skin or pushing air into the patient's tissue.

13. Claims 11 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,080,116 to Erickson et al. as applied to claim 1, in further view of U.S. 5,807,375 to Gross et al. Erickson et al. does not teach the use of an adhesive material for securing the device to the tissue. Gross et al. discloses an analyte-controlled liquid delivery and analyte monitor with a delivery needle and a sensor needle. Gross et al. discloses in column 16, lines 11-21 that an adhesive layer which is provided at the surface contact would hold the device in place throughout the analysis. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interstitial fluid collection apparatus of Erickson et al. to include an adhesive layer on the surface in contact with the skin as disclosed by Gross et al. since the adhesive layer will hold the device in place throughout the analysis. In regard to claim 26, the combination also teaches that the needle may have the enzyme layer inside the needle in lieu of an external coating as disclosed in column 21, lines 37-43 of Gross et al. which would modify the flow through the needle.

Conclusion

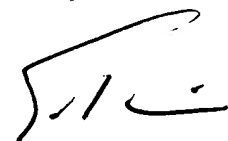
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 4,671,288 to Gough discloses an electrochemical cell sensor for monitoring oxidizable enzyme substrates in biological fluids. U.S. Patent 5,591,139 to Lin et al. (cited by Applicant) discloses and IC-processed microneedle. U.S. Patent 5,457,041 to Ginaven et al. (cited an Applicant) discloses an array of microneedles for introducing biological substances into living cells.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Matthew Kremer
Examiner
Art Unit 3736
June 12, 2001



**ERIC F. WINAKUR
PRIMARY EXAMINER**